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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/070,099	05/28/1993	KAREL NEWMAN	9197-008710	8455

7590 10/07/2004

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/070,099	Applicant(s) NEWMAN ET AL.	
	Examiner Anne Holleran	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 8 is/are allowed.
- 6) ☒ Claim(s) 1-6, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed June 21, 2004 is acknowledged. Claims 1-10 are pending and examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn:

3. The objection of claim 9 because of potentially confusing wording is withdrawn in view of the amendment to claim 9.
4. The rejection of claims 1-10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.
5. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Garrido-Pinson (Journal of Immunology, 97(6): pages 897-912, 1966; cited in the IDS) or Samloff (Journal of Immunology, 101(3): 578-586, 1968) is withdrawn in view of the amendment of claims 1 and 2, where the claimed antibodies are limited to monoclonal antibodies having the particular property of specifically binding to intrinsic factor only in the absence of vitamin B12 and exhibiting an increase in the first order dissociation rate of the antibody-intrinsic factor

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complex in the presence of vitamin B12, wherein the dissociation rate is dependent on the concentration of vitamin B12.

6. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Smolka (Gastroenterology 98: 607-614, 1990) is withdrawn in view of the amendment to claim 1.

Claim Rejections Maintained:

7. The rejection of claims 1-6, 9 and 10 under 35 U.S.C. 102(b) as being anticipated by Pourfazaneh-I (WO 91/00519; published 10 January 1991; cited in the IDS) is maintained for the reasons of record. Specifically, the previous Office action pointed to a teaching of Pourfazaneh-I, specifically pointing to a monoclonal antibody that binds to intrinsic factor alone (see page 18, line 37-page 19, line 1). Applicants' arguments did not address this teaching in Pourfazaneh-I, which appears to be drawn to a monoclonal antibody that binds to intrinsic factor in the absence of vitamin B12 (mab 5G1) that does not appear to be an antibody that binds to the vitamin-B12 binding site, because Pourfazaneh-I appears to distinguish it from antibodies that do bind to the vitamin B12 binding site. Therefore, the rejection is maintained.

Claims 1-6 are drawn to antibodies and kits comprising said antibodies, where the antibodies bind to intrinsic factor only in the absence of vitamin B12. The kits may include an antibody that binds to intrinsic factor regardless of the presence of vitamin B12. Anti-intrinsic factor antibodies that bind to intrinsic factor only in the absence of vitamin B12 read on competitive antibodies. Claims 9 and 10 are drawn to methods for the assay of vitamin B12 in a

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liquid samples comprising the use of an antibody that binds to intrinsic factor that bind only in the absence of vitamin B12.

Pourfazaneh-I teaches antibodies and monoclonal antibodies that bind to intrinsic factor, where the antibodies are competitive antibodies (see abstract and page 5, lines 8-15; page 6, line 13 – page 10, line 23. Competitive antibodies are antibodies that would bind to intrinsic factor only in the absence of vitamin B12. Additionally, Pourfazaneh-I teaches a monoclonal antibody that binds to intrinsic factor alone (see page 18, line 37 – page 19, line 1). Thus, Pourfazaneh-I teaches antibodies, kits and methods that are the same as that claimed.

8. The rejection of claims 1-6, 9 and 10 under 35 U.S.C. 102(e) as being anticipated by Pourfazaneh-II (U.S. 5,310,656; issued May 10 1994) is maintained for the reasons of record. Specifically, the previous Office action pointed to a teaching of Pourfazaneh-II, specifically pointing to a monoclonal antibody that binds to intrinsic factor alone (see col. 10, lines 17-18). Applicants' arguments did not address this teaching in Pourfazaneh-II, which appears to be drawn to a monoclonal antibody that binds to intrinsic factor in the absence of vitamin B12 (mab 5G1) that does not appear to be an antibody that binds to the vitamin-B12 binding site, because Pourfazaneh-II appears to distinguish it from antibodies that do bind to the vitamin B12 binding site. Therefore, the rejection is maintained.

Conclusion

Claims 7 and 8 are allowed. Claims 1-6, 9 and 10 are rejected.

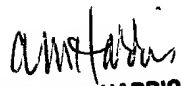
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Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
October 4, 2004


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
10/4/2004